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Plaintiffs' counsel

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

IN RE PACIFIC FERTILITY CENTER LITIGATION

This Document Relates to:
No. 3:18-cv-01586
(A.B., C.D., E.F., G.H., and I.J.)

Master Case No. 3:18-cv-01586-JSC

PLAINTIFFS' OPPOSITION TO CHART'S MOTION FOR SUMMARY JUDGMENT

Date: March 4, 2021
Time: 9:00 a.m.
Judge: Hon. Jacqueline S. Corley
Place: Courtroom F, 15th Floor

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INTRODUCTION

Defendant Chart designed and manufactured a vacuum-insulated storage tank to maintain biological samples at cryogenic temperatures with a minimal loss of liquid nitrogen each day. That tank was filled with liquid nitrogen at the close of business on March 3, 2018, but the very next day was found to have imploded and lost all liquid nitrogen. Subsequent testing revealed that one of the tank's interior welds had cracked. Plaintiffs are fertility patients whose eggs and embryos were stored in Chart's tank; they seek to hold Chart responsible for manufacturing a defective product and failing to recall or retrofit that product prior to the March 4th incident. Chart denies all responsibility and requests that summary judgment be entered in its favor.

Chart makes five arguments in support of it motion for summary judgment. First, Chart says Plaintiffs' liability expert is not qualified and without his testimony, Plaintiffs cannot show Chart's tank caused the March 4th incident. That expert is a forensic engineer who has more than thirty years of experience analyzing failed metal components and regularly taught the Failure Analysis and Prevention course at Duke University. His testimony is admissible and will be helpful to the jury in evaluating the extensive post-mortem testing that was performed on Chart's tank. But even without the assistance of an expert, the jury could reasonably conclude that Chart's product was responsible for the March 4th incident. One of Chart's own documents states that a cracked weld causes a sudden loss of vacuum and implosion, which is exactly what happened here. There is no other rational explanation for why a cryogenic tank would lose all liquid nitrogen overnight and implode. In fact, the only alternative explanation that Chart has offered requires the jury to believe that multiple embryologists are lying about keeping the tank filled with liquid nitrogen. Chart is entitled to ask the jury to disregard sworn testimony, but that is not something the Court can do at the summary judgment phase.

Second, Chart says a jury should not be permitted to use the consumer expectation test when assessing whether Chart's tank was defective in design. Chart claims the consumer expectation test is not appropriate because its cryogenic containers are complex and jurors are unlikely to have worked with them on an everyday basis. But as a recent California Court of Appeal decision affirmed, "the consumer expectation test can apply to complex or technical products, even where the use of these products may not be within the common knowledge of jurors." *Demara v. The Raymond Corp.*, 13 Cal.

App. 5th 545 (2017). The relevant question is not whether jurors use cryogenic containers, but whether those who do use them have minimum expectations that the jurors could reasonably find have not been met. Here, a jury could reasonably credit Plaintiffs' evidence that, just as a thermos is not expected to lose its cooling ability overnight, the embryologists who use Chart cryogenic containers on a daily basis do not expect those containers to suddenly lose all of their vacuum insulation, consume 14 inches of liquid nitrogen within 24 hours, and implode.

Third, Chart says a jury cannot reasonably find that it acted negligently when it failed to retrofit or recall its tank's electronic controller, which lost the ability to warn of dangerously low liquid nitrogen levels about two weeks before the March 4th incident. Chart says Plaintiffs have presented no expert testimony to establish that its electronic controllers were defective. [redacted] The fertility clinic's employees have testified that if Chart's controller had not malfunctioned, it would have sent them mobile alerts and the March 4th incident would have been averted. Under these circumstances, a jury could reasonably find that Chart's failure to retrofit or recall its electronic controller contributed to the March 4th incident.

Fourth, Chart says Plaintiffs cannot recover punitive damages because there is no evidence it intentionally concealed material facts or engaged in despicable conduct with willful and conscious disregard for the rights of others. [redacted] But rather than retrofit its defective controllers to alleviate the possibility that a weld failure would have tragic consequences, Chart did nothing. [redacted]. An award of punitive damages is

needed to deter Chart from continuing to conceal known defects that jeopardize its customers' irreplaceable biological tissue.

Fifth, Chart says Plaintiff G.H. cannot recover damages for the diminished possibility that her two frozen eggs could yield a healthy child. Multiple experts have testified that G.H.'s chances were greatly diminished by the March 4th incident, dropping from about 17% down to 2%. But Chart claims that G.H. cannot recover damages for that loss unless she can show her chances were greater than 50% before the March 4th incident. Chart's argument is based on a misunderstanding of California case law. Plaintiffs need to show that it is more likely than not that the March 4th incident contributed to G.H.'s diminished chances, not that it is more likely than not G.H. would otherwise have a baby.

The evidence that Chart is responsible for its cryogenic tank suddenly losing vacuum and imploding is considerable. Plaintiffs respectfully request they be permitted to present that evidence to a jury, and that Chart's motion for summary judgment be denied.

SUMMARY OF FACTS

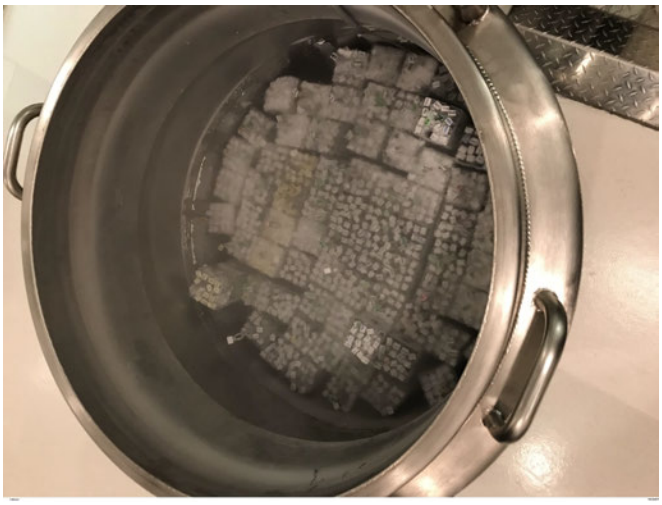
I. The March 4th incident

On Sunday, March 4, 2018, as the Laboratory Director at the Pacific Fertility Center was preparing to close up for the day, he discovered that the lid of one of the lab's cryopreservation tanks was stuck in place and condensation had pooled on the floor. (Zeman Decl., Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 100, 115-116.) That tank was called "Tank 4" and it contained 2,500 embryos and 1,500 eggs from patients who had undergone egg-retrieval or IVF procedures. (*Id.*, Ex. 33 (Pacific MSO 30(b)(6) and Romney Dep.) at 140; *id.*, Ex. 34 (MSO001984) at 1986.) The Lab Director immediately recognized something had gone seriously wrong. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 100.) Much like a thermos, cryopreservation tanks depend on a vacuum layer to insulate frozen eggs and embryos—which are stored in a bath of liquid nitrogen at -196° C—from the much warmer, room-temperature laboratory. (*Id.*, Ex. 14 (11/06/20 Report of D. Wininger, as amended on 12/04/20 ("Wininger Am. Rep.") at 8; Ex. 35 (Chart 30(b)(6) and Brooks Dep.) at 20.) The condensation was a sign the vacuum had failed and the tank was warming—endangering the previously frozen eggs and embryos. (Zeman Decl., Ex. 35 (Chart 30(b)(6) and Brooks Dep.) at 139-140.) The Lab Director and other embryologists at PFC worked quickly to transfer the

eggs and embryos to another tank, but the damage had already been done: ice crystals form when cryopreserved samples are exposed to temperatures between -150° C and -132° C, and the jagged edges of those crystals cause significant intracellular damage or cell death. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 119; *id.*, Ex. 15 (Wininger Dep.) at 68; *see also* Section VII, *infra*.)

The day before, one of PFC's embryologists had refilled Tank 4 and verified that the tank contained a sufficient quantity of liquid nitrogen. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 98-99; *id.*, Ex. 29 (Popwell Dep.) at 129-130.) Although a typical IVF tank consumes only about an inch to an inch-and-half of liquid nitrogen each day, PFC's practice was to ensure that its tanks contained at least 13 inches of liquid nitrogen at the close of business each day. (*Id.,* (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 61; *id.*, Ex. 29 (Popwell Dep.) at 41.) Embryologist Jean Popwell testified that on that particular Saturday afternoon, she filled Tank 4 up to the 14-inch mark on the tank's dipstick. *(Id.*, Ex. 29 (Popwell Dep.) at 129.) [redacted] (Zeman Decl., Ex. 69 (11/06/20 Report of J. Cauthen ("Cauthen Rep.") at 8-10; *id,*, Ex. 53 (CHART070093) at Record # 29848; *id.*, Ex. 3 (Cauthen Dep.) at 61-62; *id.*, Ex. 37 (MSO000310) at 360.) But when PFC's staff forcibly removed the tank's lid the following afternoon, the Lab Director found that Tank 4's liquid nitrogen level was down to an inch at most. *(Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 112-113.) Because the Lab Director had activated the tank's fill function before he realized something was wrong and asked for help removing the lid, that inch of liquid nitrogen was most likely newly replenished—meaning that Tank 4 had lost all of its liquid nitrogen in less than 24 hours. *(Id.* at 101, 112-113.)

After PFC staff finished removing eggs and embryos from Tank 4, they saw why the lid had been stuck in place: Tank 4's inner vessel had begun to implode. (*Id.* at 41-42, 114.) And in the hours after the tank was emptied, it continued to implode until it was a crumpled mass of stainless steel:



Normal Tank

Tank 4 after the Incident

II. Tank 4's vacuum insulation should have lasted 10 years and degraded gradually—giving PFC embryologists the warning signs they've been trained to look for.

Tank 4 was manufactured in January 2012 by Defendant Chart—a leading supplier of cryogenic containers for the IVF industry that claims to have "set the standard for storage of biological materials at low temperatures." (Zeman Decl., Ex. 38 (Chart's Answers to RFA Set 4) at Answer No. 1; *id.*, Ex. 39 (Praxair 30(b)(6) Dep.) at 36; *id.*, Ex. 40 (CHART000007) at CHART000009.) The tank was designed to maintain cryogenic temperatures with minimal evaporation of liquid nitrogen, which acts as a refrigerant for the biological material. (*Id.*, Ex. 6 (11/06/20 Report of R. Parrington ("Parrington Rep.") at 1.) Under California law, Chart may be held strictly liable if Tank 4 did not perform as safely as an ordinary consumer would have expected it to perform when used or misused in an intended or reasonably foreseeable way. *See* CACI 1203.

One of Plaintiffs' expert witnesses, David Wininger, has testified that in his opinion, Tank 4 failed to perform as safely as he and other regular users of cryogenic containers would have expected it to perform. (Zeman Decl., Ex. 15 (Wininger Dep.) at 36; *id.*, Ex. 14 (Wininger Am. Rep.) at 14.) Wininger is an IVF Lab Director who has worked with cryogenic storage containers for more than 30

years, who trains and supervises other users of cryogenic containers, and who inspects cryogenic containers at other IVF labs for the College of American Pathologists. (*Id.*, Ex. 14 (Wininger Am. Rep.) at 1-2.) As Wininger explains in his expert report, ordinary users expect cryogenic containers to be capable of safely storing sensitive biological samples at cryogenic temperatures for a minimum of ten years. (*Id.* at 14.) As the container ages, its vacuum insulation is expected to gradually degrade rather than to fail suddenly and all at once. (*Id.* at 14; Zeman Decl., Ex. 27 (CHART050770).) That gradual degradation eventually manifests in physical symptoms that the container is losing its ability to keep samples cold: the container will become cool to the touch, condensation or frost will appear on its outer walls, and it will need to be refilled with increasing frequency. (Zeman Decl., Ex. 14 (Wininger Am. Rep.) at 14-15.) But no reasonable user expects that a cryogenic container's vacuum will degrade to the point the container needs to be replaced inside of ten years, and no reasonable user expects the vacuum to fail all at once and consume more than 14 inches of liquid nitrogen in less than 24 hours. (*Id.*)

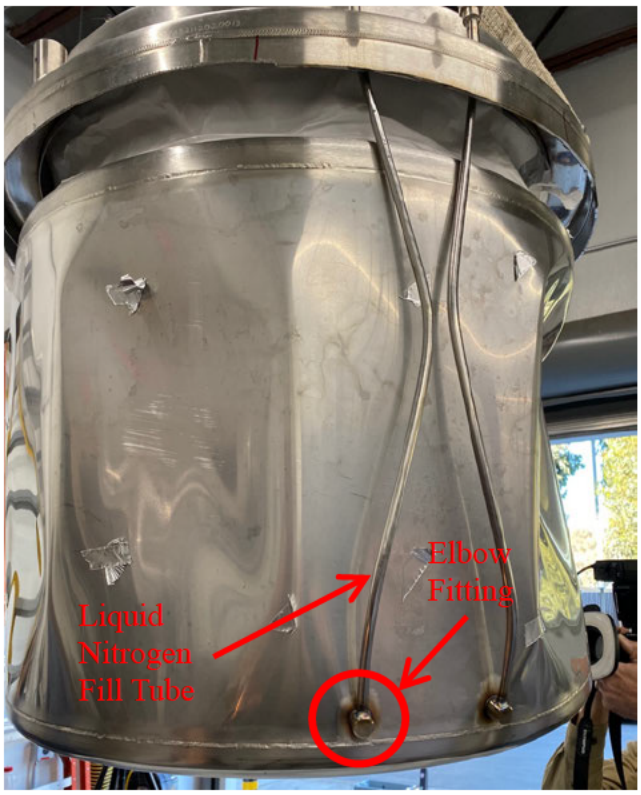
Chart's own expert and documents support Wininger's opinions and confirm that Tank 4 failed to store biological material as safely as users expect. Grace Centola, an andrologist who works with cryogenic tanks on a regular basis testified that [redacted] (*Id.*, Ex. 16 at 46.) [redacted] (Zeman Decl., Ex. 27 (CHART050770).) Chart has represented to regulators that "Chart vacuum-insulated vessels provide hold times of at least 7 DAYS," meaning that it should take at least 7 days and often much longer before a Chart cryogenic tank loses all of its liquid nitrogen to evaporation. (*Id.*, Ex. 11 (DFMECA) at BAT-0, PWR-0, PWR-10, CTL-0; *see also id.*, Ex. 41 (Junnier Dep.) at 72-73 (Chart vessels "can maintain LN2 and temperature for quite a while, for weeks on end").) [redacted] (*Id.*, Ex. 42 (CHART034331).) And Chart's medical risk

management team has assigned the possibility of a total vacuum loss like that suffered by Tank 4 to the lowest possible risk level: "So unlikely, occurrence not expected." (*Id.*, Ex. 11 (DFMECA) at DEW-3, DEW-4; *id.*, Ex. 36 (Risk Estimation).)

[redacted] (*Id.*, Ex. 43 (CHART051322).) [redacted] (*Id.*) [redacted] (*Id.*, Ex. 44 (CHART062204) at 211.)

III. A cracked weld on the inside of Tank 4 caused the March 4th incident.

The reason Tank 4's vacuum failed so suddenly was uncovered through post-mortem testing conducted by experts representing Plaintiffs, Chart, and PFC. (*Id.*, Ex. 1 (11/06/20 Report of A. Kasbekar, as amended on 11/30/20 ("Kasbekar Am. Rep.")) at 10-36.) That testing revealed a crack in a small weld on the inside of the tank—the weld that connects the tank's fill tube to the tank's inner vessel. (*Id.* at 16-19.) Chart's cryogenic tanks are manufactured with a metal tube that can be used to fill the tank with liquid nitrogen. (*Id.* at 20.) That tube runs from the top of the tank, down through the tank's vacuum insulation layer, and into the inner vessel near the bottom of the tank. The picture on the following page was taken after Tank 4's outer vessel was removed; the red circle shows where its liquid nitrogen fill tube connected to the inner vessel through an elbow fitting.



Liquid nitrogen tube feeds into Tank 4's inner vessel

(*See id.* at 25).) The fill tube's elbow fitting was then welded on the inside of Tank 4's inner vessel. That's the weld that cracked. The image on the left is a close-up up the weld, with red dye indicating a crack. [redacted]. (*Id.* at 19, 42.)

Close up of weld – red dye indicates a crack

[redacted]

CT scan of weld showing through wall crack

The crack in Tank 4's interior weld, though small, had enormous consequences for the tank and the reproductive tissue stored inside. That crack allowed liquid nitrogen to seep from Tank 4's inner vessel into its vacuum-insulation layer, where it was warmed by the surrounding laboratory air, transitioned from a liquid to a gas, and expanded to almost 700 times its original volume. (*Id.* at 59-60.) The presence of so much nitrogen gas trapped between the tank's inner and outer vessels exerted a significant amount of pressure, which is why the inner vessel imploded. *Id*. More importantly, the presence of nitrogen gas meant the vacuum insulation that had been impeding heat transfer from the tank's room-temperature surroundings had been destroyed. Heat transfer ordinarily occurs when molecules bump into other nearby molecules and transfer some of their energy. When Tank 4's vacuum layer was still intact, it contained very few molecules and so heat transfer from the outside environment to Tank 4's inner vessel was minimal. But once that vacuum layer filled with high-pressure nitrogen gas, there were plenty of molecules to facilitate heat transfer and Tank 4 was no longer capable of shielding its contents from the warm laboratory air. (*See* Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at 38.)

What happened to Tank 4 is exactly what Chart said would happen if an interior weld were to crack. Under the European Union's Medical Device Directive, Chart is required to identify every way that its cryogenic containers can fail. Chart's engineers came up with over a hundred potential failure modes. One of them was a crack or leak at the weld joining the liquid nitrogen fill line to the container's inner vessel—the very weld that cracked in Tank 4. If that weld cracked, according to Chart the result would be: "Liquid draws into vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss. Loss of function of the freezer." (*Id.*, Ex. 11 (DFMECA).)

	A	B	C	D	E	F
1	**Design Failure Mode, Effects and Criticality Analysis**					
2	**CRYOGENIC FREEZERS: MVE, HECO, VARIO, CRYOSYSTEM FULL AUTO**					
3	**ID#**	**Item**	**Item Function**	**Potential Design Failure Mode**	**Potential Cause of Design Failure Mode**	**Immed Effect of failure**
4						
47	DEW-3	Dewar- Annular lines	Fill line from the outer to inner vessel	Crack or leak	Weld Line Failure	Liquid draws into vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss. Loss of function of the freezer

Chart's Failure Analysis: weld crack causes total vacuum loss and inner vessel implosion

[redacted] (*Id.*, Ex. 45 (CHART070695) at 696.) [redacted] (*Id.*, Ex. 46 (CHART008310) at 310.)

IV. A manufacturing defect caused the cracked weld.

Post-mortem testing of Tank 4 has also revealed why Tank 4's weld cracked: it was too thin and [redacted]. (*Id.*, Ex. 1 (Kasbekar Am. Rep.) at 44-45.) [redacted]. (*Id.*, Ex. 10 (CHART070444); *id.*, Ex. 9 (Parrington Dep.) at 113-114, 139-140.) [redacted] (*Id.*, Ex. 1 (Kasbekar Am. Rep.) at 42-43, 53; *id.*, Ex. 9 (Parrington Dep.) at 113-114, 139-140.) [redacted] *Id.*, Ex. 1 (Kasbekar Am. Rep.) at 42.) [redacted]

[redacted]

(*Id.* at 52, 55.)

[redacted] (*Id.* at 38-39, 44, 60-61.) [redacted] (*Id.* at 38-39.) [redacted] (*Id.*) [redacted] . (*Id.*) [redacted] . (*Id.* at 46, 59.)

V. Design defects also contributed to the cracked weld.

Elements of Tank 4's design also contributed to its eventual failure. The fitting Chart used to join Tank 4's fill tube to its inner vessel was not designed to sit flush against the inner vessel—the fitting is flat, while the inner vessel is curved. (*Id.* at 38-39.) Chart admits both that it would have been feasible to manufacture Tank 4 with a fitting that sat flush and that there were no disadvantages to doing so. (*Id.*, Ex. 38 (Chart's Answers to RFA Set 4) at Answer No. 11; *id.*, Ex. 47 (Chart's Answers to ROG Set 6) at Answer No. 2.) [redacted]

[redacted]. (*Id.*, Ex. 1 (Kasbekar Am. Rep.) at 38-39.) [redacted]. (*Id.* at 52-53, 56.)

[redacted]. (*Id.* at 53, 57, 61-62.)

[redacted]. (*Id.* at 53, 62.)

In addition, the manufacturing defect discussed in the previous section could also be construed as a design defect. Chart contends that even though its design specifications call for a full-penetration weld, Tank 4's partial-penetration weld conformed to its design and that it "intended a seal weld … with no minimum thickness." (Zeman Decl., (Chart's Answers to RFA Set 4) at Answer Nos. 4, 6.) [redacted]

[redacted] (*Id.*, Ex. 1 (Kasbekar Am. Rep.) at 61-62.)

VI. Chart knew Tank 4's controller was defective but did not recall it.

Tank 4 came with a Chart TEC 3000 electronic controller that PFC was using to monitor the tank's conditions and sound alarms if the liquid nitrogen level dropped below 6 ½ inches. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 64-65, 72; *id.*, Ex. 53 (CHART070053) Record # 1783; *id.*, Ex. 30 (09/09/20 Conaghan Dep.) at 160; *id.*, Ex. 2 (11/06/20 Report of E. Leaphart "Leaphart Rep.") at 25; *see id.*, Ex. 48 (02/06/20 Gustafson Dep.) at 165-166.) If that controller had been working at the time of the March 4th incident, PFC would have been alerted to the sudden vacuum failure and could have moved Tank 4's eggs and embryos to the lab's backup tank before any damage was done. (*Id.*, Ex. 49 (11/20/20 Supplemental Expert Report of G. Centola ("Centola Supp. Rep.")) at 4-5; *id.*, Ex. 34 (MSO001984) at 1988-1989; *id.*, Ex. 33 (Pacific MSO 30(b)(6) and Romney Dep.) at 194; *id.*, Ex. 29 (Popwell Dep.) at 87-88.) Even if no one was in the IVF lab at the time, Tank 4's alarm system was hooked to a Sensaphone that was programmed to relay the alarm to PFC's embryologists—four of whom lived within 30 minutes of the IVF lab. (*Id.*, Ex. 30 (09/09/20 Conaghan Dep.) at 54-56, 59-61; *id.*, Ex. 34 (MSO001984) at 1988-1989.)

About two weeks before the March 4th incident, however, Tank 4's electronic controller malfunctioned. (*Id.*, Ex. 33 (Pacific MSO 30(b)(6) and Romney Dep.) at 111-112.) The controller lost its ability to accurately detect Tank 4's liquid nitrogen level and temperature: it continuously reported a liquid nitrogen level of 0 and a temperature of -273° C, even though the tank was full and the temperature of liquid nitrogen is -196° C. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 75; *id.*, Ex. 2 (Leaphart Rep.) at 31.) These false readings caused the controller to repeatedly sound false alarms and continuously add liquid nitrogen to an already full tank. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan) at 76-77, 187-189.) PFC's Lab Director tried troubleshooting the controller, but the only way he was able to stop the false alarms and continuous filling was to unplug the controller. (*Id.* at 79; Zeman Decl., Ex. 33 (Pacific MSO 30(b)(6) and Romney Dep.) at 112-113; *id.*, Ex. 34 (MSO001984) at 1986.) This was not the first time that one of the TEC 3000 controllers at PFC had malfunctioned and the Lab Director was hesitant to pay for yet another faulty controller. (*Id.*,

Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan) at 72-73.) While PFC looked into alternatives, the lab shifted to manual monitoring of Tank 4's liquid nitrogen levels—the same procedure it uses to monitor its smaller cryogenic containers. (*Id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan Dep.) at 114-115; *id.*, Ex. 34 (MSO001984) at 1986.)

Chart contends PFC should have made different choices when faced with constant false alarms and a controller that wouldn't stop filling an already full tank with liquid nitrogen. (*Id.*, Ex. 49 (Centola Supp. Rep.) at 4-5.) The extent to which PFC is to blame for the March 4th incident will be a central issue during the upcoming trial, but one thing is certain: if Chart had recalled Tank 4's controller before the March 4th incident, PFC would never have been put in that position. [redacted] (*Id.*, Ex. 50 (Gonzalez Dep.) at 33.) It had a name for the defect: "SN=0," because the controller's serial number would typically reset to 0 when it malfunctioned. (*Id.*, Ex. 77 (EXTRON-000223) at 1; *id.*, Ex. 78 (CHART031817) at subject line.) [redacted] (*Id.*, Ex. 51 (CHART004576).) [redacted] (*Id.*, Ex. 52 (Chart 30(b)(6) and Bies Dep.) at 222-223; *id.*, Ex. 54 (EXTRON000325) at 326; *id.*,Ex. 55 (CHART033664) at 665; Ex. 56 (CHART008978); *id.*, Ex. 57 (EXTRON004150); *id.*, Ex. 58 (CHART017944); *id.*, Ex. 59 (CHART038721) at 722.) [redacted] (*Id.*, Ex. 59 (CHART038721) at 722.)

- [redacted] (*Id.*, Ex. 54 (EXTRON000325) at 326.)
- [redacted] (*Id.*)

- [redacted] (Zeman Decl, Ex. 55 (CHART033664) at 665.)
- [redacted] (*Id.*, Ex. 56 (CHART008978).)
- [redacted] (*Id.*, Ex. 57 (EXTRON004150).)
- [redacted] (*Id.*, Ex. 58 (CHART017944).)
- [redacted] (*Id.*, Ex. 59 (CHART038721) at 722.)

[redacted] (*Id.*, Ex. 60 (CHART002854) at 255.) As one of Chart's field service engineers explained, "It was our thought process that this touch screen controller would be the end – hopefully the end-all, be-all to fix these interference issues." (*Id.*, Ex. 41 (Junnier Dep.) at 94-95.)

[redacted] (*Id.*, Ex. 50 (Gonzalez Dep.) at 34.) Chart also released retrofit kits that could be used on existing TEC 3000 controllers to resolve the SN=0 defect. (*Id.*, Ex. 41 (Junnier Dep.) at 94-95; *id.*, Ex. 61 (Wade Dep.) at 128-130.) But Chart never told TEC 3000 users that they needed the retrofit to resolve a known defect. (*Id.*, Ex. 41 (Junnier Dep.) at 94-96; *id.*, Ex. 61 (Wade Dep.) at 104, 129; *id.*, Ex. 73 (11/13/20 Pacific MSO 30(b)(6) and Conaghan Dep.) at 64-65.) Chart knew that facilities like PFC were continuing to use defective TEC 3000 controllers, and it knew they would often continue to use those controllers even after they malfunctioned. (*Id.*, Ex. 35 (Brooks Dep.) at 165-166; *id.*, Ex. 52 (Chart 30(b)(6) and Bies Dep.) at 228; *id.*, Ex. 41 (Junnier Dep.) at 77-79.) [redacted]

[redacted] (*Id.*, Ex. 62 (CHART028403) at 404.)

Chart was in a unique position to know just how dangerous it could be to operate one of its cryogenic tanks with a defective controller, but still did nothing. Ordinary users know that the vacuum insulation in cryogenic tanks gradually degrades as the tank ages, and they know to keep a lookout for signs that the tank is losing vacuum. (*Id.*, Ex. 14 (Wininger Am. Rep.) at 14.) But only Chart knew that an interior weld crack could cause an overnight vacuum failure in its cryogenic tanks. (*Id.*, Ex. 11 (DFMECA).) [redacted] (*Id.*, Ex. 44 (CHART062204); *id.*, Ex. 45 (CHART070695) at 696; *id.*, Ex. 46 (CHART008310) at 310.) [redacted] (*Id.*, Ex. 52 (Chart 30(b)(6) and Bies) at 54-56; *id.*, Ex. 40 (CHART000007) at 9; *id.*, Ex. 63 (CHART20048); *id.*, Ex. 64 (CHART007923).) Armed with this knowledge, Chart had a responsibility to recall or retrofit its defective TEC 3000 controllers and ensure that any future sudden vacuum failures could be detected and addressed before the biological samples inside were damaged. Even now—after the March 4th incident damaged 2,500 frozen embryos and 1,500 frozen eggs—Chart still has not publicly disclosed the SN=0 defect or recalled the defective TEC 3000 electronic controllers used by medical facilities around the country. (*Id.*, Ex. 52 (Chart 30(b)(6) and Bies Dep.) at 224.)

VII. The March 4th incident damaged Plaintiffs' eggs and embryos.

Plaintiffs' eggs and embryos were among those stored in Tank 4 during the March 4th incident. As a result of Chart's defective weld and defective controller, those eggs and embryos were subjected to hazardous conditions and irreparably damaged. (*Id.*, Ex. 14 (Wininger Am. Rep.) at 17-24.) The jagged ice crystals that form when frozen tissue is exposed to elevated temperatures caused cellular damage that greatly diminishes the likelihood that Plaintiffs' eggs and embryos will lead to a successful pregnancy. (*Id.* at 17.)

PFC cautions patients against using Tank 4 eggs and embryos, and when patients have tried, the result has been dramatically lower success rates at every step of the IVF process. (*Id.* at 46; Zeman

Decl., Ex. 66 (Herbert Dep.) at 240. 244-247; *id.*, Ex. 79 (PFC_000027) at 32; *id.*, Ex. 65 (11/06/20 Expert Report of N. Jewell ("Jewell Rep.")) ¶¶ 30-44.) The chance of achieving a live birth from a frozen egg stored in Tank 4 is now 88% lower than it was before the March 4th incident, and the chance of achieving a live birth from a frozen embryo is now 72% lower:

	Pre-Incident	Post-Incident	Change
Chance of live birth per egg	9.6%	1.2%	-88%
Chance of live birth per embryo	47.8%	13.4%	-72%

(*Id.*, Ex. 14 (Wininger Am. Rep.) ¶ 52.)

The cumulative impact on Plaintiffs' chances of having children using their frozen eggs and embryos is significant. For example, Plaintiff I.J. froze 18 eggs and before the March 4th incident could have expected those eggs would yield an average of 2.7 children, with a 95% probability that she would give birth to at least one child. But after the March 4th incident, I.J. can now only expect an average of 0.2 births and only has a 19% probability of giving birth to at least one child.

			Pre-Incident		Post-Incident	
Plaintiff	# Stored	Egg age	Exp. Births	Chance of 1+	Exp. Births	Chance of 1+
A.B./C.D.	4 embryos	29	1.9	92%	0.5	44%
E.F.	9 eggs	34	1.4	77%	0.1	10%
G.H.	2 eggs	38	0.2	17%	0.0	2%
I.J.	18 eggs	34	2.7	95%	0.2	19%

(*Id.*, ¶ 54.)

In addition, there are good reasons to avoid using Tank 4 eggs or embryos altogether. (*Id.*, ¶¶ 56-60.) As PFC's President explained, there is no information in the scientific or medical literature about the clinical or developmental consequences of using eggs or embryos that have been exposed to unsafe temperatures: "Can you imagine the experiment where you thaw a human embryo uncontrollably and then try to make a baby out of it? I don't think so." (Zeman Decl., Ex. 66 (Herbert

Dep.) at 240.) Plaintiffs' experts agree and have testified they would have serious reservations about using Tank 4 tissue in a frozen embryo transfer. (*Id.*, Ex. 14 (Wininger Am. Rep.) ¶ 60; *id.*, Ex. 67 (11/15/19 Somkuti Dep.) at 100.) Among their concerns is the number of low birthweights that have resulted when patients have used Tank 4 tissue. (*Id.*, Ex. 14 (Wininger Am. Rep.) ¶¶ 59, 60; *id.*, Ex. 68 (11/06/20 Report of S. Somkuti, as amended on 11/16/20 ("Somkuti Am. Rep.")) ¶ 29.) Low birthweights are associated with increased risk for a variety of health problems throughout one's lifetime, and of the babies born using Tank 4 tissue, 17% have been born with low birthweights—about twice the normal rate. (*Id.*, Ex. 14 (Wininger Am. Rep.) at ¶ 59.)

VIII. The March 4th incident caused Plaintiffs financial harm and emotional distress.

The impact of the March 4th incident on Plaintiffs' lives is difficult to overstate. Plaintiffs' eggs and embryos represented a substantial investment in their future; an investment for which Plaintiffs had paid a hefty price—and not just a financial price, but a physical and emotional one as well. Plaintiffs A.B. and C.D., who had four embryos in Tank 4, paid over $40,000 for their fertility treatments, while Plaintiffs E.F., G.H., and I.J. each paid between $10,000 and $20,000 to retrieve and cryopreserve their eggs. (*Id.*, Ex. 80 (A.B.'s Answers to Chart's ROGS) at Answer No. 24; *id.*, Ex. 81 (C.D.'s Answers to Chart's ROGS) at Answer No. 21; *id.*, Ex. 82 (E.F.'s Answers to Chart's ROGS) at Answer No. 21; *id.*, Ex. 83 (G.H.'s Answers to Chart's ROGS) at Answer No. 21; *id.*, Ex. 84 (I.J.'s Answers to Chart's ROGS) at Answer No. 21.1) These fertility treatments were stressful, invasive, and socially isolating. They required Plaintiffs to take daily hormone injections that cause soreness, bruising, nausea, bloating, fatigue, mood swings, irritability, restlessness, depression, and anxiety. (Zeman Decl., Ex. 68 (Somkuti Rep.) ¶¶ 20, 26.) Plaintiff E.F. recalled "how scared I was of using the needles … how I was very irritable. [My boyfriend] and I got into a lot of fights. I was crying. I felt anxious." (*Id.*, Ex. 17 (Grill Rep.) at 40.) In the days leading up to the attempted egg retrieval, Plaintiffs were required to make multiple visits to a fertility specialist for transvaginal ultrasounds and hormone level evaluations. (*Id.*, Ex. 68 (Somkuti Rep.) ¶ 19.) The added time commitments and rising uncertainty about whether their egg follicles would develop properly only added to Plaintiffs' stress. (*See, e.g., id.*, Ex. 17 (Grill Rep.) at 23.) As did the egg retrieval itself, which is a surgical procedure that requires monitored anesthesia

and involves the insertion of a hollow needle through the vaginal wall and into an ovary. (*Id.*, Ex. 68 (Somkuti Rep.) ¶ 21.)

After all Plaintiffs had invested, to learn that their eggs and embryos had been damaged in the March 4th incident and were likely no longer viable was devastating. As Plaintiffs A.B. and C.D. put it, "Those embryos were—were our family. Those were our children … you can't replace them." (*Id.*, Ex. 17 (Grill Rep.) at 49.) "The majority of our married life was spent creating those embryos—those were our world and they are gone." (*Id.* at 51.) To this day, A.B. is "always grieving the 'what if' … then there's the clash with reality and I have to deal with the grief all over again." (*Id.* at 52.)

When Plaintiff E.F. heard about the tank failure, she "cried all morning." (*Id.* at 41. Her mother came to stay with her because she was having nightmares and was "screaming in my dreams." (*Id.*) She felt like "the rug was pulled out from underneath me and instead of feeling like I was building a future, I felt stuck in quick sand." (*Id.*)

Plaintiff G.H. recalls feeling numb when she first heard about the March 4th incident and described a "mourning process of the fact that I went through this, you know, somewhat traumatic experience to buy myself some insurance. And then that insurance was destroyed. … [I]t was emotional. It was sad." (*Id.* at 32.) She thinks about her lost eggs every day. (*Id.* at 33.) Due to low ovarian reserves, G.H. was only able to retrieve and cryopreserve two eggs, but as she put it, "Two eggs are more than zero. Those were my hope." (*Id.*)

Plaintiff I.J. was filled with shock and disbelief—thinking, "Why me? Why my tank?" (*Id.* at 25.) Two months later, she "had a miscarriage, and things got really bad after that." (*Id.*) She didn't know if the stress from the March 4th incident helped to cause that miscarriage, she started to doubt her fertility, and she "became frustrated and angry that [her] insurance policy was gone." (*Id.*) As I.J. put it, "I paid to have my eggs harvested and available for when I needed them, and they're gone. Those were my 34-year-old eggs, and I can't get them back. My options have been taken from me." (*Id.* at 26.)

ARGUMENT

I. Chart is not entitled to summary judgment on the issue of causation.

A. Kasbekar's expert opinion is that Tank 4 failed due to Chart's defective weld.

In conjunction with its motion for summary judgment, Chart has moved to preclude Plaintiffs' forensic engineer, Anand Kasbekar, from testifying at trial. If that motion is granted, Chart says Plaintiffs will be unable to establish Tank 4 caused the March 4th incident and so summary judgment should be entered in its favor. (Chart's Mot. for Summary Judgment ("Chart Mot."), ECF 628, at 11-12); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (summary judgment is proper in the event of a "complete failure of proof concerning an essential element" of plaintiffs' claims).

Kasbekar is a former Adjunct Assistant Professor at Duke University with more than thirty years of experience analyzing fractured metal components. (Zeman Decl., Ex. 1 (Kasbekar Am. Rep.) at App. A.) He participated in the parties' joint inspection and testing of Tank 4, analyzed Tank 4's fracture surfaces, and intends to testify that the March 4th incident was caused by a defective weld that suffered a progressive fatigue crack. (*Id.* at 10-11, 44-51, 59-61.) That crack allowed the liquid nitrogen to seep into Tank 4's vacuum insulation layer, resulting in a total loss of Tank 4's ability to maintain its contents at cryogenic temperatures and triggering an implosion of Tank 4's inner vessel. (*Id.* at 59-61.)

Plaintiffs have separately opposed Chart's efforts to exclude Kasbekar's testimony. If Plaintiffs' arguments prevail, and Kasbekar is permitted to testify, Plaintiffs will have shown they can present admissible evidence to support their contention that Tank 4 caused the March 4th incident—making summary judgment improper. *See Cortez v. Glob. Ground Support, LLC,* No. 09-4138 SC, 2010 WL 5173861, at *5 (N.D. Cal. Dec. 15, 2010) ("Because the Court denies Defendants' challenge to Plaintiff's [expert] evidence of causation, Defendants have failed to show that Plaintiff lacks any evidence" to support the causation element of Plaintiff's product liability claims.)

B. Other evidence also suggests Tank 4 lost all its liquid nitrogen and imploded due to a manufacturing or design defect.

Even if Kasbekar were unable to testify at trial, however, summary judgment would still be inappropriate. Plaintiffs believe that expert testimony is the most helpful and efficient way to present their theory of causation to the jury, but that theory is not wholly dependent on Kasbekar's opinions.

With or without opinion testimony, Plaintiffs can introduce evidence showing a crack in Tank 4's interior weld. Numerous photographs of the crack were taken during the parties' joint post-mortem inspection of Tank 4, including those shown above, in Kasbekar's report, and in the reports submitted by Chart's forensic engineer. (*See* Summary of Facts, Section III, *supra*; Zeman Decl., ¶ 2; *id.*, Ex 1 (Kasbekar Am. Rep.) at 12-13, 17-19; *id.*, Ex. 6 (Parrington Rep.) at 16-17.) Any of the engineers and attorneys who attended that inspection can be called as percipient witnesses to describe the location of the crack and authenticate the photographs taken by those in attendance. (*See* Zeman Decl., ¶ 2.) The jury can also consider deposition testimony from Chart's expert, who agreed during his deposition that the crack was a "through crack … that went from the inner vessel on one side through to the vacuum space on the back." (*Id.*, Ex. 9 (Parrington Dep.) at 93.)

Plaintiffs also can introduce evidence showing Tank 4 failed as a result of its cracked weld. Chart's own failure modes analysis identifies that very weld as a potential cause of tank failure. (*Id.*, Ex. 11 (DFMECA) at DEW-3, DEW-4.) The document states that a crack or leak in the weld would cause liquid nitrogen to draw into the tank's vacuum space, expanding rapidly and causing an inner vessel implosion, total vacuum loss, and loss of function of the freezer—exactly what happened to Tank 4. (*Id.*) [redacted] (Zeman Decl., Ex. 45 (CHART070695) at 696.)

Finally, Plaintiffs can introduce evidence that a manufacturing or design defect is responsible for the crack. A product contains a manufacturing defect if it differs from the manufacturer's specifications, and it contains a design defect if the product is manufactured as intended but nonetheless is a substantial factor in causing harm or fails to perform as safely as an ordinary user would have expected. *See* CACI 1201-1204; *Johnson v. United States Steel Corp.*, 240 Cal. App. 4th 22, 32 (2015). [redacted]. (*Id.*, Ex. 10 (CHART070444); *id.*, Ex. 70 (Ingram Dep.) at 49-50, 66; *id.*, Ex. 9 (11/16/20 Parrington Dep.) at 113-114, 139-140.) And even if Tank 4 were manufactured as intended, Chart has admitted that its design

included "no minimum thickness," which might reasonably have contributed to the weld eventually cracking. (*Id.*, Ex. 38 (Chart's Answers to RFA Set 4) at Answer No. 1.) Plaintiffs have also presented considerable evidence that Tank 4 failed to perform as safely as an ordinary user of cryogenic containers would have expected it to perform. (*See* Summary of Facts, Section II, *supra*.)

A jury faced with this evidence could reasonably conclude that the March 4th incident was caused by a manufacturing or design defect, making summary judgment inappropriate. *See Anderson v. Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). Expert testimony would certainly be helpful to the jury, but it is not required. For example, in *Pierson v. Ford Motor Company*, the Ninth Circuit found that even without the assistance of an expert, there was sufficient evidence from which the jury could infer that a deficient latch in Ford's van caused the plaintiff's injuries. *Pierson,* 445 F. App'x 966, 968-69 (9th Cir. 2011). So, too, here, where even without expert testimony, Plaintiffs' evidence establishes that PFC filled Tank 4 with 14 inches of liquid nitrogen on March 3rd, (Zeman Decl., Ex. 3 (Cauthen Dep.) at 61-62; *id.*, Ex. 37 (MSO000310) at 360; *see id,*, Ex. 53 (CHART070093) at Record # 29848-28835); less than 24 hours later, Tank 4 had lost all of that liquid nitrogen and had begun imploding, (*id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan) at 41-42, 112-113); post-mortem inspections revealed a cracked in one of Tank 4's interior welds, (*id.*, ¶ 2); and Chart's own failure modes analysis states that a cracked interior weld causes a total loss of vacuum insulation and an implosion ,(*id.*, Ex. 11 (DFMECA) at DEW-3, DEW-4.)

The only alternative explanation that Chart has presented is that PFC lied, failed to fill Tank 4 with liquid nitrogen in the days or weeks leading up to the March 4th incident, and Tank 4 spontaneously imploded as a result—causing the weld to crack from PFC's abuse rather than because Chart manufactured a product with a defective weld. (Chart's Mot. To Exclude Kasbekar and Wininger, ECF No. 629, at 14; Zeman Decl., Ex. 5 (11/20/20 Supplemental Report of F. Miller) at 23-24.) If Chart can persuade a jury to disregard PFC's sworn testimony and digital records and buy into its spontaneous-implosion theory, it may then be entitled to judgment on the issue of causation. But at this stage in the proceedings, the Court must credit PFC's testimony and draw all reasonable inferences in Plaintiffs' favor. *Anderson*, 477 U.S. at 255. And at least one reasonable inference that can be drawn from PFC's testimony, the physical evidence, and Chart's own records is that Tank 4 suffered an

overnight vacuum failure and began imploding due to a defective weld. *See also Hill-Jones v. Gen. Elec. Co.*, No. 14-cv-2636-JGB, 2015 WL 12732713, at *3 (C.D. Cal. May 5, 2015) ("the plaintiff in a strict liability action is not required to disprove every possible alternative explanation of the injury in order to have the case submitted to the jury") (quoting *Campbell v. Gen. Motors Corp.*, 32 Cal. 3d 112, 121 (1982)).

II. Chart is not entitled to summary judgment under the consumer expectation test for a design defect.

There are two alternative tests for a design defect: (i) the consumer expectation test, which asks whether a product performs as safely as an ordinary consumer would have expected it to perform; and (ii) the risk-benefit test, which asks only whether the product's design was a substantial factor in causing plaintiffs' harm, but also gives the defendant an opportunity to show that the benefits of its design outweigh the risks. CACI 1203, 1204; *Demara v. The Raymond Corp.*, 13 Cal. App. 5th 545 (2017). Both tests may be used in the same case, and the instructions given to the jury are required to make it clear that the two tests are alternatives. *Id.*

Chart nonetheless contends that the consumer expectation test is not suited for this case because Tank 4 was a complex product and not within the everyday experience of an average juror. (Chart Mot. at 12-13.) California courts have affirmed, however, that "the consumer expectation test can apply to complex or technical products, even where the use of these products may not be within the common knowledge of jurors." *Demara*, 13 Cal. App. 5th at 561 (applying test to forklift). If a product has a specialized use making it unfamiliar to the general public, the jury may still apply the consumer expectation test based on the minimum expectations of those persons who do use the product. *Vanier v. Bagttery Handling Sys., Inc.*, No. CV S-O6-978 LKK/PAN, 2007 WL 2688731, at *6 (E.D. Cal. Sept. 12, 2007) (applying test to battery gantry). As one California court explained, "there are certain kinds of accidents—even where fairly complex machinery is involved—which are so bizarre that the average juror, upon hearing the particulars might reasonably think, 'Whatever the user may have expected from that contraption, it certainly wasn't that.'" *Id.* (quoting *Akers v. Kelley, Co.*, 173 Cal.App.3d 633, 650, 219 Cal. Rptr. 513 (1985)). Moreover, expert testimony can be used to help the jury understand what a

specialized product's actual consumers expect from the product. *Soule v. Gen. Motors Corp.*, 8 Cal. 4th 548, 567, n.4 (1994).

Even if complexity matters, cryogenic containers are not particularly novel or complicated devices. PFC describes its tanks to its patients as "really like giant thermos flasks on wheels" and "in effect like a large thermos flask since its vacuum lined." (*Id.*, Ex. 71 (MSO018818) at 820; *id.*, Ex. 72 (PLTF-ABCD-001031) at 1034); *see also id.*, Ex. 32 (10/09/19 Pacific MSO and Conaghan Dep.) at 172-173.) [redacted] (*Id.*, Ex. 48 (02/06/20 Gustafson Dep.) at 21; *id.*, Ex.35 (Chart 30(b)(6) and Brooks Dep.) at 20-21; *see also id.*, Ex. 22 (12/01/20 Miller Dep.) at 16 [redacted]".) Chart points out that its cryogenic tanks are sometimes used with electronic controllers, but that controller is optional and was not in use on Tank 4 at the time of the March 4th incident. The issue for the jury is not whether Chart's TEC 3000 controller performed as expected, but whether Chart's cryogenic container performed as expected. The jury may need to understand something about vacuum insulation and metal welds to make that determination, but neither concept is particularly complex and both are common features of products that consumers do use on an everyday basis.

Ultimately, in deciding whether to instruct the jury on the consumer expectations test, the critical questions for the Court are not whether jury members are familiar with cryogenic containers or whether cryogenic containers are complex. *Demara*, 13 Cal. App. 5th at 558-59; *Vanier,* 2007 WL 2688731 at *7. The critical questions are whether ordinary users of cryogenic containers would have minimum expectations about their safety for storing biological tissue, and whether the circumstances of Tank 4's failure permit an inference that those minimum expectations were not met. *Id.* Plaintiffs have presented evidence that permits the Court to answer both questions in the affirmative. One of Plaintiffs' experts, David Wininger, is an IVF Lab Director who has worked with cryogenic containers for thirty years, trained and supervised embryologists to work with cryogenic containers, and inspected other IVF labs' cryogenic containers for the College of American Pathologists. (Zeman Decl., Ex. 14 (Wininger Am. Rep.) ¶¶ 1-2.) He has testified that ordinary users of cryogenic containers, like Wininger himself and the lab staff he works with on a daily basis, expect those containers to be capable of safely storing

biological material, expect the containers' vacuum insulation to degrade gradually rather than suddenly and all at once, and expect the containers to show physical symptoms when they begin losing their ability to keep samples cold. (*Id.*, Ex. 15 (Wininger Dep.) at 36-37, 55-56, 65-66; *id.*, Ex. 14 (Wininger Am Rep.) ¶¶ 37-42.) The way that Tank 4 failed—losing its vacuum insulation overnight, consuming 14 inches of liquid nitrogen in less than 24 hours, and imploding—is well beyond what any ordinary user of cryogenic tanks would reasonably expect. (*Id.; see also* Ex. 16 (Centola Dep.) at 46.) Under these circumstances, the jury would be well-justified in concluding that Tank 4 failed the consumer expectations test for a design defect. Plaintiffs' respectfully request that the Court give jury members that chance and deny Chart's request for summary judgment. *See Demara*, 13 Cal. App. 5th at 562 (reversing summary judgement where "jurors could reasonably find that these ordinary consumers of the [forklift] could form certain minimum safety assumptions and expectations for the product"); *Vanier,* 2007 WL 2688731 at *7 ("defendant has not shown as a matter of law that the defect alleged here is of such a technical nature that the ordinary user … could not have any assumptions about the minimum safety of that aspect of the product").

III. Chart is not entitled to summary judgment on Plaintiffs' claim for failure to recall or retrofit Tank 4's controller.

A. The evidence shows Chart's failure to recall or retrofit was a substantial factor that contributed to the damage caused by the March 4th incident.

In addition to holding Chart strictly liable for defects that existed when Tank 4 was manufactured, Plaintiffs also seek to hold Chart liable for negligently failing to recall or retrofit Tank 4 after learning that its electronic controller suffered from the dangerous "SN=0" defect. *See Hernandez v. Badger Constr. Equip. Co.*, 28 Cal. App. 4th 1791, 1827–28 (1994) ("Failure to conduct an adequate retrofit campaign may constitute negligence apart from the issue of defective design."). Chart seeks an entry of summary judgment on this claim, as well. (Chart Mot. at 13-15.) It says Plaintiffs' liability theories are inconsistent: "[t]he alleged weld failure has nothing to do with the controller," and Plaintiffs therefore cannot show that Chart's failure to recall or retrofit that controller could have caused them harm.

Chart is correct that Plaintiffs contend the most immediate cause of the March 4th incident was a crack in Tank 4's defective weld. But an injury may have more than one contributing cause: "A defendant's negligent conduct may combine with another factor to cause harm … a defendant cannot avoid responsibility just because some other person, condition, or event was also a substantial factor in causing the plaintiff's harm." *Yanez v. Plummer*, 221 Cal. App. 4th 180, 187 (2013); *see also* CACI No. 431. Here, the evidence shows that if Chart had retrofitted Tank 4's controller prior to the March 4th incident, that retrofitted controller would have alerted PFC that Tank 4's liquid nitrogen levels were dropping due to a sudden loss of vacuum, and PFC could have transferred Plaintiffs' eggs and embryos to a backup tank before they were damaged. (Zeman Decl., Ex. 49 (Centola Supp. Rep.) at 4-5; Ex. 33 (Pacific MSO 30(b)(6) and Romney Dep.) at 194; *id.*, Ex. 29 (Popwell Dep.) at 87-88; *id.*, Ex. 34 (MSO001984) at 1988-1989. .) [redacted] (*Id.*, Ex. 59 (CHART038721) at 722.) But with this knowledge and even though Chart had a retrofit available to fix the defect, it failed to retrofit Tank 4 prior to the March 4th incident. (*Id.*, Ex. 41 (Junnier Dep.) at 94-96; *id.*, Ex. 61 (Wade Dep.) at 104, 128-130.)

Chart also failed to issue a recall notice to PFC, which could have alerted PFC that Tank 4's controller suffered from a known defect; that a retrofit was available to fix that defect; and that it was critically important for Tank 4's controller to be replaced immediately because, while rare, sudden vacuum failures had been known to occur in Chart's cryogenic tanks. (*Id.*, Ex. 73 (11/13/20 Pacific MSO 30(b)(6) and Conaghan Dep.) at 64-65; *id.*, Ex. 41 (Junnier Dep.) at 94-95; *id.*, Ex. 61 (Wade Dep.) at 104, 128-130; *id.*, Ex. 11 (DFMECA) at DEW-3, DEW-4.) By March 4th, PFC had experienced the defect first-hand and had asked its supplier for a solution, but it had yet to receive a replacement for its malfunctioning TEC 3000 controller. (*Id.*, Ex. 21 (MSO024063).) PFC did not know that the issue was caused by a known defect in the TEC 3000 or that a ready fix was available, and expected that manual monitoring would be sufficient in the interim. (*Id.*, Ex. 33 (Pacific MSO and Romney Dep.) at 114-115; *id.*, Ex. 30 (09/09/20 Conaghan Dep.) at 19.) Chart knew that customers like PFC continued to use their cryogenic tanks after the controller malfunctioned and it knew why: customers expect that any loss in the tank's ability to maintain cryogenic temperatures will occur

gradually due to normal degradation in the tanks' vacuum insulation—not suddenly and all at once. (*Id.*, Ex. 35 (Brooks Dep.) at 165-166; *id.*, Ex. 52 (Chart 30(b)(6) and Bies Dep.) at 228; *id.*, Ex. 27 (CHART050770).) Only Chart knew just how dangerous it was to operate one of its cryogenic tanks without a controller, even on a temporary basis. (*Id.*, Ex. 11 (DFMECA) at DEW-3, DEW-4; *id.*, Ex. 43 (CHART051322); *id.*, Ex. 44 (CHART062204).) [redacted] (*Id.*, Ex. 62 (CHART028403) at 404.).)

This evidence is sufficient to establish that both Chart's failure to retrofit Tank 4's controller and its failure to issue an appropriate recall notice caused harm to Plaintiffs' eggs and embryos. California's causation standard requires only that Chart's failure to retrofit or recall Tank 4 contribute to the March 4th incident—it need not be the sole cause and its contribution need only be "more than negligible or theoretical." *Rutherford v. Owens-Illinois, Inc.*, 16 Cal. 4th 953, 978 (1997); *see also* CACI No. 430. The evidence suggests that Chart's failure to retrofit or recall Tank 4's controller was indeed a contributing factor, and that if Chart had installed a retrofit or issued an appropriate recall notice, the tank's eventual weld failure could have been detected and damage to Plaintiffs' eggs and embryos averted.

B. The evidence establishes Chart owed Plaintiffs a duty to recall or retrofit Tank 4.

Chart focuses its argument on causation, but also suggests that Chart did not owe Plaintiffs "any duty to recall the controller." (Chart Mot. at 14.) It cites *Montez v. Ford* to support its position, but that case says little about a manufacturer's duty to remedy a known defect; it held only that the trial court's failure to instruct the jury on negligence was harmless because the jury found defendants' product was not defective—a finding that was fatal under both negligence and strict liability theories of recovery. *Montez v. Ford Motor Co.*, 101 Cal. App. 3d 315, 319 (1980).

Subsequent cases have confirmed that under circumstances such as these, a defendant does indeed have a duty to its customers to conduct an adequate retrofit campaign. For instance, in *Lunghi v. Clark Equipment Company*, where the defendant manufacturer learned of the dangerous propensities of its machine after the product had been on the market for a while, the California Court of Appeal held that a reasonable jury could find that the manufacturer's knowledge created a duty to conduct an

adequate retrofit campaign. *Lunghi v. Clark Equip. Co.*, 153 Cal. App. 3d 485, 494 (1984). And in *Hernandez v. Badger*, the California Court of Appeal similarly found that the evidentiary record "supports a finding [defendant] breached its duty to conduct an adequate retrofit campaign." *Hernandez v. Badger Constr. Equip. Co.*, 28 Cal. App. 4th 1791, 1828 (1994). Like Chart, the manufacturer in that case had addressed a known safety issue in newly manufactured products but decided not to retrofit the products it had already sold. *Id.* Based on that evidence, the court found "the jury could properly conclude [defendant] did not do 'everything reasonably within its power to prevent injury' to plaintiffs." *Id.* at 1828; *see also Hensley-Maclean v. Safeway, Inc.,* No. CV 11-01230 RS, 2014 WL 1364906, at *6 (N.D. Cal. Apr. 7, 2014) (denying summary judgment where "numerous California decisions have explicitly or implicitly recognized that a seller's duty under negligence may extend beyond the point of sale")

As in *Lunghi* and *Hernandez*, the evidence presented by Plaintiffs supports a finding that Chart owed them a duty to conduct an adequate retrofit campaign. [redacted] (Zeman Decl., Ex. 50 (Gonzalez Dep.) at 33.) It knew that the TEC 3000 was used to monitor eggs, embryos, and other sensitive biological tissue. (*Id.*, Ex. 52 (Chart 30(b)(6) and Bies) at 54-56; *id.*, Ex. 40 (CHART000007) at 9; *id.*, Ex. 63 (CHART20048); *id.*, Ex. 64 (CHART007923).) And it had addressed the defect in future controllers and developed retrofit kits to fix the issue in existing controllers, but still failed to retrofit Tank 4's controller or even inform PFC that the retrofit was available. (*Id.*, Ex. 73 (11/13/20 Pacific MSO 30(b)(6) and Conaghan Dep.) at 64-65; *id.*, Ex. 41 (Junnier Dep.) at 94-95; *id.*, Ex. 61 (Wade Dep.) at 104, 128-130.) A jury hearing these facts could reasonably conclude that Chart's knowledge imposed on them a duty to either conduct an adequate retrofit campaign or issue an appropriate recall notice to customers like PFC.

C. Plaintiffs' claim does not require expert testimony.

Chart also objects that Plaintiffs' evidence is not in the form of expert testimony. But expert testimony is not the only form of evidence upon which a jury can reasonably rely in finding that Chart negligently failed to retrofit or recall Tank 4's controller prior the March 4th incident. The need for

expert testimony depends upon the facts of each case. *See Pierson,* 445 F. App'x at 968-69. Courts faced with arguments like Chart's will often wait until after trial to determine if the evidence presented is sufficient to establish a defective product contributed to plaintiffs' injuries, or whether expert testimony is necessary. *See Lexington Ins. Co. v. Schrader-Bridgeport Int'l, Inc.,* No. 09-1509 SC, 2010 WL 11586816, at *3 (N.D. Cal. June 2, 2010); *NBTY, Inc. v. Sw. Forest Prod., Inc.*, No. CV 12-00872-JEM, 2013 WL 5651564, at *1 (C.D. Cal. Oct. 15, 2013).

Here, expert testimony is not necessary to establish that TEC 3000 controllers suffer from a dangerous defect that causes them to lose the ability to accurately monitor liquid nitrogen levels. Chart's own deposition testimony and its own internal documents establish that TEC 3000 controllers suffered from that very defect, that Chart had a name for the defect, and that Chart knew it was important "to take action immediately." (Zeman Decl., Ex. 59 (CHART038721) at 722; *id.*, Ex. 77 (EXTRON-000223) at 1; *id.*, Ex. 78 (CHART031817) at subject line.) Chart's electrical expert, Eldon Leaphart, does not disagree—in fact, he discusses the SN=0 defect in his report and cites some of the same deposition testimony that Plaintiffs intend to rely upon at trial to describe the malfunction. (*Id.*, Ex. 2 (Leaphart Rep.) at 34; *id.*, Ex. 74 (Leaphart Dep.) at 76 ("Q. Have you ever heard of the serial number equals zero issue? A. From reviewing materials received, yes.".) Leaphart also testified that Tank 4 displayed the symptoms of the SN=0 defect, as did multiple witnesses who worked with the controller at PFC. (*Id.*, Ex. 74 (Leaphart Dep.) at 76; *e.g.*, *id.*, Ex. 32 (10/09/19 Pacific MSO 30(b)(6) and Conaghan) at 74-77; *id.*, Ex. 33 (09/10/19 Pacific MSO 30(b)(6) and Romney) at 111-112.) Under these circumstances, where Plaintiffs can prove the existence of a defect through several alternate avenues, there is no reason to also require them to do so through expert testimony. *See United States v. Mirama Enterprises, Inc.*, 185 F. Supp. 2d 1148, 1160 (S.D. Cal. 2002) ("The Court does not require expert testimony to find that a reasonable person *could* conclude that the juicer contained a defect," where manufacturer was informed of at least 23 prior incidents).

Nor is an expert witness necessary to establish that Chart owed Plaintiffs a duty to recall or retrofit Tank 4, or that its failure to do so contributed to Plaintiffs' injuries. As the *Hernandez* and *Lunghi* cases illustrate, duty can be established through proof of the defendants' knowledge and, here, that knowledge is evident from Chart's documents and does not require expert credentials to appreciate.

Hernandez, 28 Cal. App. 4th at 1827–28; *Lunghi*, 153 Cal. App. 3d at 494. Similarly, Plaintiffs can demonstrate Chart's failure to retrofit or recall Tank 4's controller contributed to Plaintiffs' injuries without using expert testimony. (*See* Argument, Section II, *supra*.) PFC's lab staff have adequately explained how a functional controller would have alerted them that Tank 4's liquid nitrogen levels had dropped below 6.5 inches and afforded them time to transfer Plaintiffs' eggs and embryos to a backup tank before irreversible damage occurred. (Zeman Decl., Ex. 53 (CHART070053) Record # 1783; *id.*, Ex. 30 (09/09/20 Conaghan Dep.) at 160; *id.*, Ex. 33 (Pacific MSO 30(b)(6) and Romney Dep.) at 194; *id.*, Ex. 29 (Popwell Dep.) at 87-88; *id.*, Ex. 34 (MSO001984) at 1988-1989.) In fact, Chart claims that PFC should be deemed contributorily negligent for not replacing Tank 4's controller on its own. (*Id.*, Ex. 49 (Centola Supp. Rep.) at 4; *id.*, Ex. 16 (11/23/20 Centola Dep.) at 215-217.) If a jury could reasonably conclude that PFC's failure to replace Tank 4's controller in the 17 days preceding the March 4th incident contributed to Plaintiffs' injuries, as Chart contends, it should also be permitted to conclude that Chart's failure to replace Tank 4's controller in the 3 years preceding the March 4th incident contributed to Plaintiffs' injuries. *See Yu Lian Tan v. Coast Crane Co.*, No. C-10-3570 MMC, 2013 WL 749514, at *2 (N.D. Cal. Feb. 27, 2013) (Defendant "has not cited to any authority suggesting that such question of causation is, in this instance, a matter exclusively within the purview of experts.").

IV. Chart is not entitled to summary judgment on Plaintiffs' claim for punitive damages.

Chart also seeks partial summary judgment on the issue of punitive damages. (Chart Mot. at 15-16.) Plaintiffs contend that by hiding the TEC 3000 defect from its customers and repeatedly failing to retrofit or recall affected cryogenic tanks, Chart engaged in intentional concealment as well as in despicable conduct that was carried out in willful and conscious disregard for the rights of others. *See* Civil Code 3294 (a), (c)(1). The evidence shows that Chart knew its customers used Chart cryogenic tanks to store eggs, embryos, and other sensitive biological tissue and used Chart TEC 3000 controllers to monitor liquid nitrogen levels inside the tank. (Zeman Decl., Ex. 52 (Chart 30(b)(6) and Bies) at 54-56; *id.*, Ex. 40 (CHART000007) at 9; *id.*, Ex. 63 (CHART20048); *id.*, Ex. 64 (CHART007923).) [redacted]

[redacted] (*Id.*, Ex. 59 (CHART038721) at 722.) [redacted] (*Id.*, Ex. 50 (Gonzalez Dep.) at 33; *id.*, Ex 41 (Junnier Dep.) at 95.) Chart even had a retrofit available that would have fixed the problem, but chose not to tell customers about it. (*Id.*, Ex., 41 (Junnier Dep) at 96; *id.*, Ex. 61 (Wade Dep.) at 128-130.) [redacted] (*Id.*, Ex. 62 (CHART028403) at 404.)

A jury faced with these facts could reasonably conclude that Chart intentionally concealed material facts or acted despicably and with willful and conscious disregards for the highly sensitive and often irreplaceable biological tissue stored in its cryogenic tanks. *See Pfeifer v. John Crane, Inc.*, 220 Cal. App. 4th 1270, 1300-01 (2013) (affirming punitive damages where defendant did not share what it knew about the dangers of its products with users). Chart was in a unique position to know what could go wrong with its tanks and how quickly those tanks could lose their ability to keep samples safely stored at cryogenic temperatures. Chart knew that its interior welds could crack, and that when they did, the tanks' vacuum insulation would be instantly compromised and the tank would implode. (Zeman Decl., Ex. 11 (DFMECA) at DEW-3, DEW-4.) And it knew that its customers would sometimes continue to use their TEC 3000s after the controllers malfunctioned, not expecting that the vacuum insulation could fail overnight. (*Id.*, Ex. 35 (Brooks Dep.) at 165-166; *id.*, Ex. 52 (Chart 30(b)(6) and Bies Dep.) at 228; *id.*, Ex. 30 (09/09/20 Conaghan Dep.) at 19.) It was therefore foreseeable to Chart that something like the March 4th incident would occur unless Chart first retrofitted or recalled its TEC 3000 controllers. In fact, given how long Chart withheld its knowledge from customers and how many TEC 3000 controllers continue to be used to help monitor biological tissue, it was inevitable that a malfunctioning TEC 3000 controller would contribute to a catastrophic loss of biological tissue.

[redacted] (*Id.*, Ex. 64

(CHART007923).) [redacted] (*Id.*) And even after the March 4th incident demonstrated the tragic consequences of deliberately keeping its customers in the dark, Chart still has not altered its conduct. [redacted] (Zeman Decl., Ex. 75 (CHART015541) at 542.) [redacted] (*Id.*, Ex. 76 (CHART058287).) [redacted] (*Id.* at 287.) Nearly three more years have elapsed since the March 4th incident, and Chart still has not publicly disclosed the SN=0 defect or informed customers that a retrofit is available to fix the defect. Without an award of exemplary damages sufficient to deter this sort of conduct, it appears that Chart will never disclose or meaningfully address the defect. *See Johnson & Johnson Talcum Powder Cases*, 37 Cal. App. 5th 292, 334 (2019) ("A defendant's entire course of conduct may be considered for purposes of assessing punitive damage awards, including post-injury conduct.")

V. Chart is not entitled to summary judgment on Plaintiff G.H.'s claim for damages related to the diminished possibility of achieving a live birth.

Chart's final request for summary judgment is limited to Plaintiff G.H., who has low ovarian reserves but was able to harvest and cryopreserve two mature eggs that were stored in Tank 4. (Zeman Decl., Ex. 68 (Somkuti Rep.) ¶51.) Like the other Plaintiffs, G.H. suffered severe emotional distress as a result of the March 4th incident and seeks an award of economic and non-economic damages sufficient to compensate her for the loss of her reproductive tissue. (*Id.*, Ex. 17 (Grill Am. Rep.) at 28-35.) Chart says that a portion of those prospective damages are unrecoverable and asks the Court to find as a matter of law that the March 4th incident did not cause her a "diminished possibility of achieving a live birth." (Chart Mot. at 17.)

Chart's argument relies on two cases. In one, the trial court granted nonsuit after plaintiffs' experts could not say with a reasonable degree of medical certainty that defendant's birth control pills caused plaintiff's cervical cancer. *Jones v. Ortho Pharm. Corp.*, 163 Cal. App. 3d 396, 404 (1985). In

the other, the trial court granted nonsuit after plaintiffs failed to show with a reasonable degree of medical certainty that negligent care was a substantial factor in bringing about the decedent's death. *Bromme v. Pavitt*, 5 Cal. App. 4th 1487, 1492 (1992).

Chart likens the absence of medical certainty in those cases to G.H.'s chances of giving birth. Just as the chance that birth control caused cervical cancer was less than 50% in *Jones*, and the chance that medical negligence brought about decedent's death was less than 50% in *Bromme*, Chart says the chance G.H. would be able to give birth using her two frozen eggs was less than 50%. But giving birth is not akin to cancer or death; it is not an injury. The injury is G.H.'s diminished possibility of achieving a live birth. Plaintiffs' evidence on that point is uncontested and shows that G.H.'s chances dropped from 17% to 2% as a result of the March 4th incident. (Zeman Decl., Ex. 14 (Wininger Am. Rep.) ¶ 54.) G.H.'s fertility options have likewise been diminished by the March 4th incident, as she is now 42 years old with diminished ovarian reserves and no longer a good candidate for egg preservation or IVF procedures. (*Id.*, Ex. 68 (Somkuti Rep.) ¶¶ 53, 65.)

Chart is fixated on the fact that G.H.'s chances of giving birth using her frozen eggs was always less than 50%, but that is not the probability that matters—what matters is whether Plaintiffs' evidence establishes a greater than 50% possibility that the March 4th incident caused G.H.'s chance of giving birth to drop from 17% to 2% and diminished her fertility options. The *Bromme* case recognizes there is a distinction: "The issue presented in this case is not the degree to which defendant's post-June 1981 acts may have contributed to Bromme's death, but the degree of certainty as to whether those acts contributed at all." *Bromme*, 5 Cal. App. 4th at 1499.

Here, the degree of certainty as to whether the March 4th incident contributed to G.H.'s lower chances of achieving a live birth is well above 50%. None of the three experts who testified that the March 4th incident caused G.H. to suffer diminished fertility potential expressed any uncertainty. (*See* Zeman Decl., Ex. 14 (Wininger Am. Rep.) ¶¶ 52-54; *id.*, Ex. 65 (Jewell Rep.) ¶ 26; *id.*, Ex. 68 (Somkuti Rep.) ¶¶ 53, 65.) In fact, Plaintiffs retained an expert in biostatistics, Prof. Nicholas Jewell, to determine whether the lower chances of obtaining a live birth using Tank 4 tissue could be attributed to something other than the March 4th incident. (*See id.*, Ex. 65 (Jewell Rep.) ¶¶ 16, 22-29.) Jewell found the pre-Incident and post-Incident IVF success rates were strongly statistically different, with p-values

under 0.001, meaning that the statistical likelihood that the March 4th incident is responsible for the diminished possibility of achieving a live birth is greater than 99.9%. (*See id.*, ¶¶ 30-42, 65, 71; *see also id.*, Ex. 85 (10/15/19 Report of N. Jewell) ¶ 41 (discussing p-values).)

Plaintiffs have, in other words, established to a reasonable degree of certainty that the March 4th incident caused a diminished possibility of achieving a live birth. The lack of certainty that led to nonsuits in *Jones* and *Bromme* is not present here and should not be used to limit the damages that Plaintiff G.H. can request at trial. *See Uriell v. Regents of Univ. of Cal.*, 234 Cal. App. 4th 735, 746 (2015) (*Jones* and *Bromme* do not apply if the plaintiff can present evidence that defendants' conduct was likely a substantial factor in causing harm).

CONCLUSION

For the reasons stated, Plaintiffs request that the Court deny Chart's motion for summary judgment and permit the case to proceed to trial.

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Respectfully submitted,

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